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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,615	06/13/2001	Michael W. Johnson	S63.2-9949	7299

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EXAMINER

COZART, JERMIE E

ART UNIT	PAPER NUMBER
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3726

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,615

Applicant(s)

JOHNSON, MICHAEL W.

Examiner

Jermie Cozart

Art Unit

3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 23, 25, 26, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (5,843,172) in view of Solovay (5,769,884).

Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent), and subsequently cutting the stent from the tube. Yan also discloses the step of disposing a treatment agent on the stent. The cutting step includes forming a plurality of openings (52) which are elongate. The cutting step also includes forming a plurality of openings (68) whose widths exceed their lengths. *See column 2, lines 7-14; column 6, lines 61-column 7, line 7; column 7, lines 30-52; and Figures 2, 6, and 8 for further clarification.*

Yan, however, does not disclose the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, or a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 6) and each region having substantially the same porosity about its circumference, wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity. *See column 3, line 41 – column 6, line 55, and Figures 2, 6, 6A, and 6D for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, and wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity, in light of the teachings of Solovay, in order to effectively deliver different amounts of medication to a particular site within the human body.

3. Claims 23-30 and 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter in view of Solovay (5,769,884) and Saunders (5,780,807).

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8', 9') of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8', 9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal.

Richter discloses a plurality of serpentine bands or segments (Fig. 11) extending about the circumference of the stent, and at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. Richter discloses openings (Fig. 11) which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment including a first side wall (Fig. 11) and a second side wall (Fig. 11) extending between and connecting the first and second serpentine segments. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. *See column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.*

Richter, however, does not disclose the following: the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference; a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube being characterized by a second porosity different from the first porosity; disposing a treatment agent on the stent; a first band having a different porosity than a second band; subsequently cutting the stent from a tube; the cutting step including forming a plurality of serpentine segments which extend about the circumference of the stent; the cutting step including forming a plurality

of openings which are elongate; the cutting step including forming a plurality of openings whose widths exceed their length; or cutting a plurality of openings in the tube to form a stent.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 5 and 6) wherein each region has substantially the same porosity about its circumference, and wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity. Solovay also discloses disposing a treatment agent (col. 6, lines 47-55) on the stent via of the stent covering. Solovay as shown in Figures 5A-5E discloses first and second fibers or bands with different porosities. See column 3, line 41 – column 6, line 55, and Figures 2 and 5A-6E for further clarification.

Saunders'807 discloses cutting a stent (10) from a tube (21), wherein the cutting step including forming a plurality of serpentine segments (30) which extend about the circumference of the stent, forming a plurality of openings (not labeled) which are elongate and whose widths exceed their length, and cutting a plurality of openings in the tube (21) to form a stent (10). See column 6, line 64 - column 7, line 22, and Figures 4-6 for further clarification.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention the provide tube of Richter with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, wherein a first portion of the

tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity, to dispose a treatment agent on the stent of Richter, to provide the tube of Richter with a first band having a different porosity than a second band, to cut the stent of Richter from a tube, wherein the cutting step includes forming the plurality of serpentine segments which extend about the circumference of the stent, to form the plurality of openings which are elongate and whose widths exceed their length, and to cut the plurality of openings in the tube to form the stent, in light of the teachings of Solovay and Saunders'807, in order to effectively deliver different amounts of medication to a particular site within the human body and to provide a precision cut stent enabling greater precision reliability, structural integrity and overall quality without burrs or other imperfections.

Response to Arguments

4. Applicant's arguments filed 10/28/04 have been fully considered but they are not persuasive.

Applicant argues that Solovay does not disclose starting with a tube of different porosities and cutting a stent from therefrom, and thus even if the references were somehow combined, there is no suggestion or teaching in the combination to start with a tube having different porosities.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the Examiner maintains that Solovay discloses providing a tube with longitudinally spaced regions of different predetermined porosities. Solovay is analogous art as it is concerned with providing the desired porosity for a stent as is the purpose of applicant's invention. Solovay achieves that purpose by providing a tube that is identical in size and structure to a stent, wherein the tube is machined to have the proper porosity. Solovay inherently teaches that the tube has already been formed into a stent-like tube, and then the tube is provided with the longitudinally spaced regions of different predetermined porosities. Solovay was only used in each of the rejections to show a tube having longitudinally spaced regions of different predetermined porosities, each of the base references in the rejections account for forming a tube with different predetermined physical characteristics (e.g. porosity, composition) and then cutting a stent from the tube. Solovay teaches making patterns of holes to form corresponding longitudinal regions of different porosity using a laser.

In the case of Yan, Yan discloses that the stent can be cut from a tube using a laser. So therefore the openings/pores will be formed in the tube prior to cutting the finished stent from the tube. It is evident based on the teachings of Yan at column 7, lines 45-49, that the stent has already been formed with holes prior to being cut from the tube. The forming of holes in the tube is part of the manufacturing process, and when

the stent is finally cut from the tube the stent will already have holes/openings throughout its length. To further reiterate this point, the tube will essentially be provided with holes/opening prior the final cutting of the stent of the stent from the tube. If you form the stent from the tube using a laser and you state that stent has cavities/openings it is clearly apparent that the cavities/openings were formed prior to cutting a finished stent from the tube since the cavities/openings were obviously formed in the tube during the initial stages of manufacturing.

In the case of Richter/Saunders, Richter/Saunders as modified discloses cutting a stent from a tube, wherein it is apparent during the initial stages of manufacturing the stent, holes/openings will be formed in the tube. Solovay provides teaches that holes/openings can be provided in longitudinal regions wherein the regions will have different porosities, so therefore when the stent is finally cut from the tube not only will it have serpentine segments it will have longitudinal regions of different porosity.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the references used in the rejection cited above to provide a tube with longitudinally spaced regions of different predetermined porosities in order to effectively deliver different amounts of medication to a particular site within the human body.

Conclusion

5. This is a continuation of applicant's earlier Application No. 09/880,615. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL**

even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

6. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 571-272-4690. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID P. BRYANT
PRIMARY EXAMINER



JC
November 19, 2004